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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ian Clarke

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,842	Applicant(s) CLARKE ET AL.	
	Examiner Philip R. Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7,9-11,15 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7,9-11,15 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/09 has been entered.

Response to Amendment

In the reply filed 4/30/09, applicant amended claim 1 and added new claim 21. Claims 1, 2, 4, 7, 9-11, 15, and 19-21 are currently pending.

Response to Arguments

The declaration under 37 CFR 1.132 filed 7/30/09 is insufficient to overcome the rejection of claims 1, 2, 4, 7, 9-11, 15, and 19-20 based upon 35 USC 103(a) as set forth in the last Office action because:

The declaration states that Laing does not teach the application of pressure at a constant rate, but fluctuates between an upper and lower threshold. Further, item 14 of the declaration compares data from the claimed device against "typical thresholds estimated from independently assessed data for a pump with an electronic control unit,

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of which Laing is a classic example." These statements have not been found persuasive.

First, there is no evidence that the electronic control unit utilized by Laing is the same as the device tested by applicants. These units can be programmed to a variety of threshold values depending on the specific needs of the operation. It is important to note that applicant is attempting to differentiate the claimed device from the prior art by stating that the claimed device operates at a perfectly constant level throughout the operation, while the prior art devices are only capable of operating within a predetermined threshold. However, the data presented in the declaration shows that even applicant's device does not function at a constant pressure, and has a degree of fluctuation over time. It is impossible for a pressure regulator to maintain a perfectly constant pressure level, and changing the threshold level of the Laing device may easily be accomplished by reprogramming the device or using a more sensitive sensor.

Second, applicant's declaration states that the difference between the claimed device and the prior art is the ability to maintain a constant pressure (i.e. a very small threshold). Even if Laing's device was not capable of maintaining a pressure threshold small enough such that the pressure is considered to be substantially constant, it has been held that the mere optimization of ranges does not constitute a patentable improvement in the art (see MPEP § 2144.05., II.). In this case, Laing clearly states the need for *constant fluid flow from the treatment bag*, and recognizes that constant flow is achieved by maintaining a constant pressure within the chamber (see Page 13, Line 10 through Page 14, Line 5). Therefore, one of ordinary skill in the art would have

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recognized that Laing's fluid infusion device may be utilized to deliver a substantially constant flow of fluid to a patient.

Applicant's arguments filed 7/30/09 have been fully considered but they are not persuasive.

Applicant argues that the prior art does not teach or suggest application of pressure at a constant and predetermined level throughout operation of the device. This argument has not been found persuasive for the reasons listed above (see the response to the declaration filed 7/30).

Applicant also argues that there is no motivation to modify the Laing device with Keime's monitoring of gas pressure (rather than fluid pressure) because Keime's device does not typically require constant delivery rate. This argument has not been found persuasive. Keime clearly teaches that the fluid outflow rate may be modified by changing the air pressure in the chamber. As discussed in the previous action, one of ordinary skill in the art would have been motivated to modify Laing's infusion device with Keime's air pressure feedback in order to provide an alternate means for controlling fluid flow rate.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 7, 9-11, 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laing (CA 2,083,555) in view of Keime (GB 2,165,312).

3. With respect to Claims 1, 2, and 4, Laing discloses an apparatus 10 for controlled dispensing of a liquid from a flexible bag 40 comprising a substantially gas-tight chamber 20 adapted to contain the flexible bag 40, and an outlet (48 and 49) adapted to receive an outlet conduit 45 communicating with the flexible bag 40. A source of gas 58 is arranged to release gas into the chamber 20, applying pressure to the exterior walls of the flexible bag 40, and a pressure regulator 50 is operable to self-regulate the pressure applied to the bag throughout the dispensing process, thus causing fluid to be dispensed from the bag in a controlled manner. The pressure regulator 50 comprises a microprocessor 56, an air pump 58, and a transducer 55. Regarding Claim 2, the air bag portion 30 of the chamber 20 is substantially air tight. The outlet (48 and 49) comprises a clamp 28 and a needle 29 adapted to seal the chamber (Page 11, Lines 3-26), and the gas supply 58 is operable to supply gas under pressure to the interior of the chamber 20. The liquid outlet from the chamber is sealed to the outlet conduit in a way that effectively prevents liquid from leaking outside of the conduit. The pressure regulator 50, which comprises air pump 58, microprocessor 56, and pressure transducer 55, is arranged to regulate the flow of gas from the source to the chamber (Page 12, Lines 15-20). Laing, however, does not specifically disclose that the pressure

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regulator self-regulates the pressure based on pressure feedback from the *gas* in the chamber (Laing uses pressure feedback from the liquid instead).

Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a substantially gas-tight chamber to initiate fluid flow. The device further comprises a pressure regulator 23 and pressure relief valve 22 that are capable of controlling the air pressure in the chamber. The pressure regulator is disposed at the inlet to the chamber, between the gas source and the flexible bag, and regulates the pressure in the chamber *based on the pressure within the chamber*. Although the desired pressure is initially overshoot by about 10 millibars, it is quickly stabilized to the desired pressure shortly thereafter. Although the regulator 23 is adapted for manual control, it is fully capable of being used to regulate the pressure within the chamber, and Keime clearly suggests that maintaining a specific gas pressure within the chamber is the ultimate goal of the regulator (see Page 2, Lines 30-85). The automation of a manual activity does not constitute a patentable improvement over the prior art. See MPEP § 2144.04 [Section III]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Laing with the pressure regulator and pressure relief valve of Keime in order to provide an alternate means for regulating the air pressure within the chamber based on the current gas pressure within the chamber.

4. With respect to Claims 4 and 19, Laing further discloses that the source of gas 58 is connected to an inflatable bladder 30 such that the inflatable bladder is in contact

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with at least a portion of the exterior wall of the air bag 40. See Figure 1. Regarding claim 19, the pressure regulator is operable to regulate the flow of gas from the source into the inflatable bladder (Page 7, Lines 14-26).

5. With respect to Claim 7, Laing discloses that the inflatable bladder 30 comprises an inflatable sock positioned and operable to wrap around at least a portion of the flexible bag 40 (see Figure 1). An “inflatable sock” is interpreted by the examiner as being any type of bag that is capable of being filled with air.

6. With respect to Claims 10 and 11, Laing discloses that the source of gas is a reservoir 35 pressurized by a pump 58 (see Figure 1). The pump 58 is controlled by the microprocessor 56 in order to change the pressure in the inflatable bladder, thus controlling the flow rate of fluid from the flexible medical supply bag.

7. With respect to Claim 20, Laing discloses that the apparatus comprises a first chamber 10 comprising a flexible bag and a second chamber (50, 52) comprising the source of gas (air pump 58) and the pressure regulator 50.

8. With respect to Claim 9, Laing discloses the portable injector of claim 1 (see rejection above) wherein air is pumped into the chamber 30 by pump 58. Laing does not disclose that the source of gas comprises a pressure vessel of precompressed gas. Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a chamber to initiate fluid flow. The device further comprises a pressure regulator 23 that is capable of controlling the amount of air infused into the chamber, thus controlling fluid flow. Therefore, it would have been obvious to one of ordinary skill

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in the art at the time of invention to modify the portable injector of Laing with the pressurized gas source of Keime in order to provide an alternate means for pressurizing the chamber to create fluid flow from the bag. The use of pressurized gas sources to pressurize a chamber is well established in the art of fluid flow.

9. With respect to Claim 15, Laing discloses the portable injector of Claim 1 and that the chamber 10 has a depth significantly less than the length and width of the chamber (see Figure 1). Laing, however, does not disclose that the pressure vessel and pressure regulator are located alongside the chamber in a common housing. Keime discloses a portable injector wherein the pressure vessel 18 and pressure regulator (21, 23) are located alongside the chamber 4 in a common housing arranged in a cuboidal configuration such that the pressure vessel and pressure regulator are contained within the depth of the housing (see Figures 1 and 2). Repositioning the pressure vessel and regulator within the chamber housing will improve the portability of the device. Additionally, integration of components and changes of shape are mere obvious matters of engineering choice and do not represent a patentable improvement over the prior art. See MPEP § 2144.04.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laing in view of Keime, and further in view of Brown (US 4,666,430). Laing and Keime reasonably suggest the device substantially as claimed, but do not specifically teach that the pressure regulator comprises a compression spring-controlled piston having a

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needle valve. Brown teaches a device for delivering a constant gas pressure from a compressed gas source 12 to a destination. The device is controlled by a pressure regulator comprising a compression spring-controlled piston that only allows gas to flow when a specific amount of pressure is applied to the piston (see Figures 5 and 6). The constant pressure applied by the gas source 12 acts on a compressible fluid source to urge the fluid source out of its container at a constant rate (see abstract and Column 2, Line 45 through Column 3, Line 13). This type of valve is well known in the art as a means for applying a constant pressure to a fluid source, thereby providing constant fluid flow. Furthermore, the use of needle valves is extremely common in the art because they provide a cost-effective means for providing a fluid-tight connection between two flow paths (see Pauliukonis (US 4,033,378), or any other typical needle valve as is known in the art). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid delivery device of Laing and Keime with the pressure regulator of Brown in order to provide a well known, alternate means for providing a constant pressure to a chamber, thereby providing a constant liquid flow out of the bag.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
17 August 2009